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Mohan Krishnan

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EXAMINER

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/731,421
Filing Date: December 09, 2003
Appellant(s): KRISHNAN ET AL.

For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 12/8/2009 appealing from the Office action mailed 7/8/2009.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,149,542	THOREN	4-1979
5,318,572	HELLAND ET AL,	6-1994

4,101,984

MACGREGOR

7-1978

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Appellant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5, 7, and 9-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thoren (US 4,149,542) in view of Helland et al. (US 5,318,572).

Claim 1	THOREN disclosure	HELLAND disclosure
A lead body extending from proximal to distal end	Figs. 1-4	

A ring electrode coupled to the lead body	Ring electrode 5 as seen in Fig. 1	
wherein the lead body and ring electrode each have an outer surface adapted to passively prevent formation of clots	Distal tip electrode and lead body is inert and thereby prevents clotting (e.g. Col. 3, line 11)	
wherein the outer surface of the lead body is adapted such that a layer of blood cells is formed on the outer surface when exposed to the blood stream	Side component is configured to promote tissue ingrowth through pores and grooves (Col. 3, line 35-52), thus creating a layer of blood cells when exposed to the blood stream	
wherein the outer surface of the ring electrode includes a textured coating including titanium microspheres		titanium microspheres between 10-200um Col. 5, lines 62-66; Col. 10, lines 19-20; Col. 6, line 16

Thoren discloses an endocardial lead with a lead body extending from proximal to a distal end. Thoren discloses a titanium ring electrode (e.g. side component 5) that

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is textured with pores to allow for tissue ingrowth and a distal tip electrode that is inert and thereby prevents clotting (e.g. Col. 2, line 24- Col. 3, line 52).

Thoren fails to explicitly teach the use of titanium microspheres for texturing the ring electrode and the lead body. Helland teaches that it is known to use titanium microspheres between 75-100um to form a layer of blood cells around the lead body electrode as set forth in e.g., column 5, lines 62 -66; column 10, lines 19-20, Col. 6, line 16; for providing the predictable results of immobilizing and stabilizing the electrode and lead body upon implantation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Thoren with use of a textured coating of titanium microspheres between 75-100um to form a layer of blood cells around the ring electrode and lead body for providing the predictable results of immobilizing and stabilizing the ring electrode and lead body upon implantation.

Examiner considers Helland to teach the microspheres allowing a layer of blood cells to form as blood passes through the pores created by the microspheres (e.g. Col. 6, line 16). Further Examiner must consider the textured microspheres to also prevent clot formation since the microsphere textured surface is of the same material and size as appellant's claimed textured surface.

With regard to claim 9, Thoren discloses no active coating that elute from the surface of the lead to minimize clotting.

Claims 1, 5, 7, and 9-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thoren in view of Helland and in view of MacGregor (US 4,280,514).

Thoren discloses an endocardial lead with a lead body extending from proximal to a distal end. Thoren discloses a titanium ring electrode (e.g. side component 5) that is textured with pores to allow for tissue ingrowth and a distal tip electrode that is inert and thereby prevents clotting (e.g. Col. 2, line 24- Col. 3, line 52).

Helland teaches that it is known to use titanium microspheres between 75-100um to form a layer of blood cells around the lead body electrode as set forth in e.g., column 5, lines 62 -66; column 10, lines 19-20, Col. 6, line 16;for providing the predictable results of immobilizing and stabilizing the electrode and lead body upon implantation.

MacGregor teaches that it is known to select the particle size and orientation of sphere particles on an electrode surface to provide the predictable results of promoting tissue ingrowth while at the same time preventing clot formation through formation of flattened endothelial-like cells which confer thromboresistance (e.g. Col. 2, line 59- Col. 3, line 22).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system as taught by Thoren with use of a textured coating of titanium microspheres between 75-100um, and to orient the spheres to form a layer of blood cells around the electrode and lead body for providing the predictable results of immobilizing and stabilizing the electrode and lead body upon implantation and promoting tissue ingrowth while at the same time preventing clot formation through formation of flattened endothelial-like cells which confer thromboresistance.

(10) Response to Argument

Appellant argues that Thoren in view of Helland, and Thoren in view of Helland and in view of MacGregor, fail to teach the outer surface of the lead body is adapted such that a layer of blood cells is formed on the lead body.

Examiner respectfully disagrees. Examiner has considered the textured surface of the side component ring electrode as disclosed by Thoren would provide for a layer of blood cell adhesion, as explicitly taught by Thoren, and the blood cells would adhere to each other, thereby creating a layer extending beyond the length of the ring electrode and further extending onto the lead body portion. It is of not that the lead body and ring electrode only be "adapted" such that a layer of blood cells be formed on the lead body, and the claims, as written do not require the lead body itself to have a textured surface for providing for blood cell adhesion.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Joseph Stoklosa/

Examiner, Art Unit 3762

3/10/2010

Conferees:

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Supervisory Patent Examiner, Art Unit 3766

/Michael Phillips/

RQAS